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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/642,772	08/18/2003	Meir Rosenberg	022719-0046	3663

21125 7590 10/07/2008

NUTTER MCCLENNEN & FISH LLP
WORLD TRADE CENTER WEST
155 SEAPORT BOULEVARD
BOSTON, MA 02210-2604

EXAMINER	
HOEKSTRA, JEFFREY GERBEN	
ART UNIT	PAPER NUMBER
3736	

NOTIFICATION DATE	DELIVERY MODE
10/07/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No.	Applicant(s)	
	10/642,772	ROSENBERG, MEIR	
	Examiner	Art Unit	
	JEFFREY G. HOEKSTRA	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-25 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. In response to the Pre-Appeal Brief Conference decision mailed on 07/28/2008 the following new grounds of rejection are set forth:

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 2, 4, 5, 15, and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Purdy et al. (US 2003/0097082 A1, hereinafter Purdy).

4. For claims 1, 2, 4, 15, and 16, Purdy discloses, an implantable fluid management device (90) (as best seen in Figures 14 and 15), comprising:

- an elongate catheter (92) (as best seen in Figures 14 and 15) (paragraphs 131-133 and 136) having a proximal end (the lower end as seen in Figure 14), a distal end (the upper end as seen in Figure 15), a first inner lumen extending therethrough (the center lumen in Figure 15), and a second inner lumen (the lumen defined by element 96 as seen in Figure 15) extending therethrough that is isolated from the first lumen (as best seen in Figures 14 and 15), wherein the second lumen is formed within an invagination of the outer wall of the catheter extending within the first lumen (as best

seen in Figures 14 and 15) (paragraphs 131-133 and 136), and wherein the first lumen has a diameter that is greater than a diameter of the second lumen (as best seen in Figures 14 and 15);

- a pressure sensor (94) embedded in a distal portion of the catheter and configured to measure a pressure of fluid surrounding the distal portion of the catheter (paragraphs 131-133 and 136) (as best seen in Figure 17);
- at least one wire (96) having a distal end coupled to the sensor (as best seen in Figures 15 and 17) and having a proximal end that is adapted to mate to an external component for powering and/or communicating with the sensor (paragraphs 133 and 136), the at least one wire disposed within the second lumen and extending along a length of the catheter such that the at least one wire is in fluid isolation from the inner lumen of the catheter (as best seen in Figure 15), wherein the sensor is disposed with a wall of the catheter such that the sensor is adapted to sense conditions adjacent to the catheter (paragraphs 131-133 and 136), and wherein the at least one wire is separable from a proximal portion of the catheter (paragraph 133) such that the length of the catheter is capable of being selectively adjusted.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 3, 6-11, 13, 15-25, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Purdy in view of Fonger et al. (US 5,291,896, hereinafter Fonger).

7. Purdy discloses the claimed invention, as set forth, cited above, and including the limitations of claims 11, 19, 20, and 27, except for expressly disclosing:

- for claims 3, 6-9, 18, 21-23, a slit extending through an outer wall of the catheter into the second lumen along at least a portion of a length thereof such that a portion of the at least one wire can be at least partially removed from the catheter through the slit to allow the length of the catheter to be selectively adjustable, wherein the slit extends along a distance less than the length of the catheter and less than about one half the length of the catheter, wherein the slit is substantially fluid impermeable in a closed position,
- for claims 10, 13, 24, and 25, wherein the catheter is made from a flexible, biocompatible polymer that is self-sealing, and
- for claim 17, wherein the sensor has a diameter that is equal to or less than about 3 mm.

8. For claims 3, 6-10, 13, 15-18, and 20-25, Fonger teaches an implantable fluid management device, comprising *inter alia*:

- a catheter (12) having an outer wall (15) and a first inner lumen (40),
- a pressure sensor (14),

- at least one wire (24) disposed within a second lumen (42) in fluid isolation from said first lumen and coupled to the sensor and proximally mated to an apparatus for electrical powering and/or communicating that extends along the length of the catheter, the at least one wire being separable from the catheter such that the catheter length is selectively adjustable (column 2 lines 30-35 and column 4 lines 32-44), and
- a slit (46) (as best seen in Figure 1) extending through the outer wall of the catheter into the second lumen along at least a portion of a length thereof such that a portion of the at least one wire can be at least partially removed from the catheter through the slit to allow the length of the catheter to be selectively adjustable (column 2 lines 30-35 and column 4 lines 32-44), wherein the slit extends along a distance less than the length of the catheter and less than about one half the length of the catheter (as best seen in Figure 1), wherein the slit is substantially fluid impermeable in a closed position (as best seen in Figure 1),
- wherein the catheter is made from a flexible, biocompatible polymer (column 3 lines 41-42) that is capable of self-sealing, and
- wherein the sensor has a diameter that is equal to or less than about 3 mm (the pressure sensor is disposed within said second lumen having an inner diameter of 10 French (column 3 lines 63-66) which is equal to approximately 3.3 mm or 0.131 inches).

9. For claims 3, 6-9, 18, 21-23, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. I of the component parts are known in Purdy and Fonger. The only difference is the combination of the component parts into a single device. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the components as taught by Purdy the components as taught by Fonger to achieve the predictable results of providing a catheter having a slit to allow the length of the catheter to be selectively adjustable.

10. For claims 10, 13, 24, and 25, the claims would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Because both Purdy and Fonger teach catheter devices, it would have been obvious to one skilled in the art at the time of the invention to substitute one catheter for the other to achieve the predictable results providing a biocompatible catheter for use in an animal body to avoid a biological immune response therein.

11. For claim 17, the claims would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Because both Purdy and Fonger teach pressure sensors having a size, it would have been obvious to one skilled in the art at the time of the invention to substitute one size of pressure sensor for the other to

achieve the predictable results providing a pressure sensor sized for sensing pressure in small regions of an animal's body.

12. Claims 12 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Purdy in view of Fonger and in further view of Quackenbush (US 5,104,398).

13. Purdy in view of Fonger disclose the claimed invention, as set forth and cited above, except for expressly disclosing the polymer selected from a group consisting of silicones, silicone-like materials, and polyurethanes and the at least one wire is disposed within a secondary catheter coupled to the first that can be peeled apart to allow the catheter length to be adjusted independent the length of the secondary catheter.

14. Quackenbush discloses a membrane splitting tube (10) comprised of polyurethane (column 3 line 23) with a catheter or wire inserted in an outer peel-away membrane (column 1 lines 33-41).

15. The claimed invention would have been obvious because a person of ordinary skill at the time of the invention would have a good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense. Thus, it would have been obvious to a person of ordinary skill in the art at the time of the invention to try using a polyurethane catheter with a secondary catheter or wire inserted in an outer peel-away membrane as taught by Quackenbush in an attempt to provide a catheter with a selectively adjustable length, as a person with ordinary skill has a good reason to

pursue the known options within his or her technical grasp. In turn, because the catheter, wire, and secondary catheter as claimed have the properties predicted by the prior art, it would have been obvious to make a catheter having at least one wire running therethrough, which is coupled to a sensor disposed at a distal portion of the catheter, and wherein an outer peel-away membrane is provided to selectively adjust the length of a catheter.

Response to Arguments

16. Applicant's arguments with respect to claims 1-25 and 27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J.H./
Jeff Hoekstra
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736